

A review of the application of sanitary surveys in Europe

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The European Food Hygiene Regulation (EC) No. 854/2004, effective from 1 January 2006, required that an assessment be made of sources of pollution of bivalve mollusc fisheries (a sanitary survey) prior to an area being classified. The Community Reference Laboratory (CRL) Guide to Good Practice for the Microbiological Monitoring of Bivalve Mollusc Harvesting Areas (GPG), produced by an EU expert working group, gave recommendations on the implementation and application of sanitary surveys. Significant experience has been gained in applying sanitary surveys in a European context. The benefits of the process have been recognized by both the authorities and the industry. However, it has been identified that some of the approaches recommended in the GPG should be modified to benefit from that experience. Possible revisions are explored in light of both the European experiences and the outputs of an International Workshop on Sanitary Surveys held at the CRL in September 2008.

Keywords: Bivalve mollusk, Escherichia coli, sanitary survey, pollution, microbiology

Introduction

The current approach to sanitary surveys in the EU is based on a combination of regulatory requirements and guidance. Regulation (EC) No 854/2004 (European Communities 2004) states that if the competent authority decides in principle to classify a production or relaying area, it must:

- (a) make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
 - (b) examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;
 - (c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area;
- and
- (d) establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must

ensure that the results of the analysis are as representative as possible for the area considered.

The European Commission Directorate General for Health and Consumers (DG Sanco) has expressed the view that sanitary surveys should be applied to:

- New mollusc harvesting areas or harvesting areas that did not have a classification by 1 January 2006 when the hygiene Regulations came into force.
- Areas that the competent authority reclassify. This include areas where the classification status has been upgraded and where it has been downgraded.

The Commission view is being discussed with Member States to determine whether this approach should be changed. The possibility of taking a risk-based approach to the need for sanitary surveys for, and classification of, offshore shellfish beds is one element of this. The need for good information on which to base a risk assessment is shown by the example given in Figure 1. This shows a diagram of an offshore mussel bed identified for classification. Both the industry interests and the local authority campaigned for the bed to be classified as A, without the need for monitoring, based on the distance offshore (approximately 3 km) and absence of potential sources of pollution. Monitoring was, however, instituted and results of up to >18000 *Escherichia coli* per 100 g were obtained. Further enquiry revealed the presence of the long sea outfall.

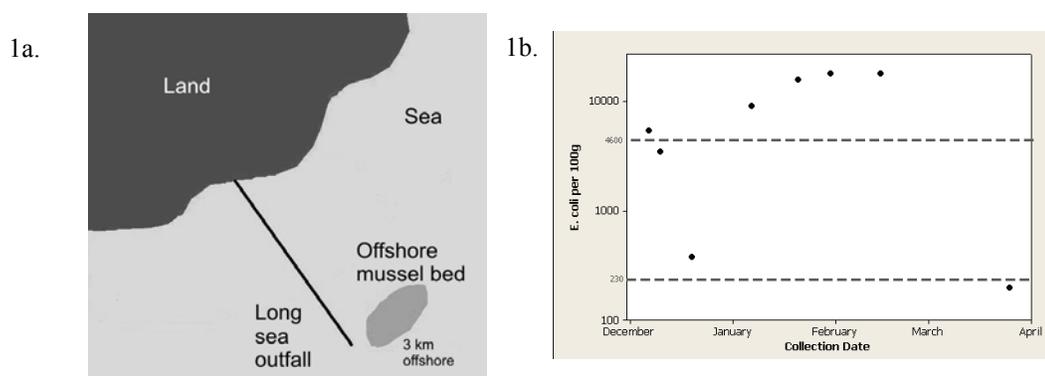


Figure 1. Schematic diagram of an offshore fishery (1a) and a scatterplot of *E. coli* monitoring

The Guide to Good Practice for the Microbiological Monitoring of Bivalve Mollusc Harvesting Areas (Technical Application) (GPG), published by the Community Reference Laboratory (CRL), recommended that: for all harvesting areas classified as at 31 December 2005, Member States should introduce a programme of work by 1 January 2009 to complete sanitary surveys by 1 January 2011 at the latest (Anon 2007). This recommendation was to avoid two levels of harvesting areas – those areas newly identified since 1 January 2006 where the monitoring programmes would be based on sanitary surveys, and the bulk of areas already classified at that date where the monitoring programmes would be based on more empirical approaches.

The dates identified in the recommendation were based on the assumption that Member States would be able to start programmes relatively quickly after the publication of the Regulation. In fact, there was a delay during which relevant training was provided by the CRL, and then cascaded to relevant officials/scientists within Member States. Resources then needed to be identified, procedures developed and programmes planned. Therefore practical work did not start until 2007 in some Member States and was only expected to start in others during 2009. The recommendation is still considered valid but the dates need to be reviewed to accommodate the delay in commencing programmes.

1. GPG recommendations on content of sanitary surveys

The GPG recommended that the sanitary survey should have four components. The first was a desk study that should largely be based on information and data already held by government agencies and other bodies and which should address the following elements: Fisheries; Point sources (continuous and intermittent); Land use; Farm animals; Wildlife; Ships and boats; Meteorology.

The second was a practical shoreline survey which should aim to practically confirm the main findings of the desk study (particularly with respect to the fishery and potential sources of faecal contamination) and to determine whether other identified sources of faecal contamination were present. The third component was an assessment of the bathymetry and hydrodynamics in the area to determine the effect of dilution and currents on the way the identified contamination sources impacted on the shellfishery(ies). The last element was an optional bacteriological survey to supplement the other three elements when the outcome of the assessment has not been conclusive. Given that information on all relevant sources of pollution may not be available, it is preferable if a bacteriological survey is undertaken for all new areas without a monitoring history. A flowchart from the GPG showing the main elements of the process is presented in Figure 2.

2. Progress with implementation in the EU

A review undertaken by the CRL identified that, at mid-2009, approximately 60 sanitary surveys had been completed across the EU. Most of these had been undertaken in two Member States, the UK (with the majority) and France. The surveys in these Member States had covered both new and existing harvesting areas. Small numbers of sanitary surveys had been undertaken in five other Member States. At least four others identified that they planned to start sanitary surveys during 2009. Most of these other Member States are concentrating on new areas only. All but one Member State identified that they were, or would be, following the recommendations of the GPG in applying sanitary surveys.

Sanitary survey and production of sampling plan

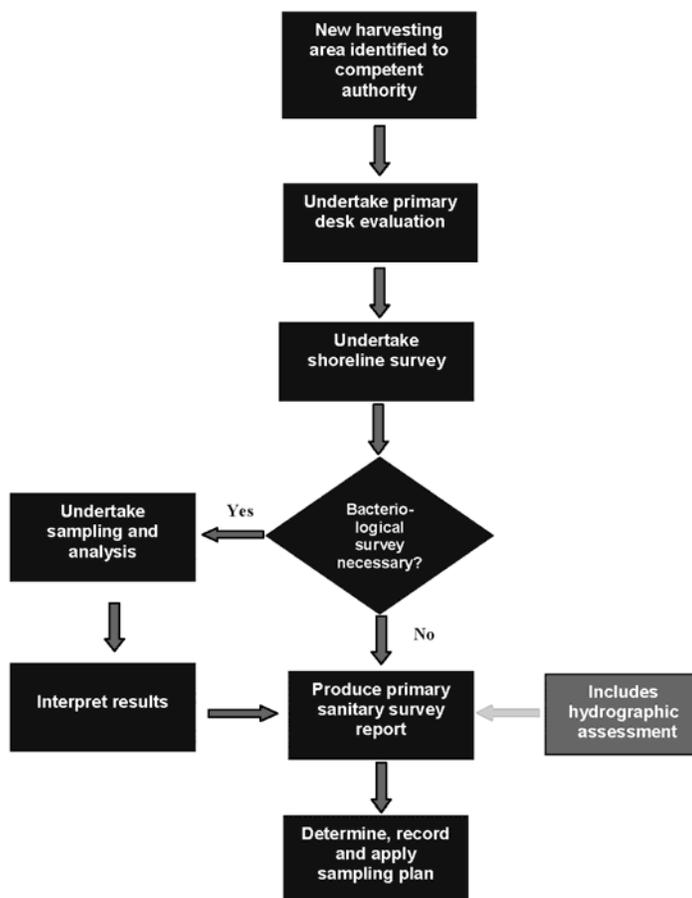


Figure 2. Flow diagram for the conduct of a sanitary survey for a new harvesting area

There is a problem in differences in interpretation of the term “new area”. Some Member States are using the term to apply to any new aquaculture area or wild shellfishery, even if this is located within an area that has been classified on the basis of the presence of other shellfisheries. This approach then may trigger a review of the basis of the sampling plan of the broader area and thus results in a sanitary survey covering both the new and existing shellfisheries. Others are restricting the term to cover only new broad areas and have not

undertaken surveys for new operations within existing areas. The Member States taking the latter approach have tended not to progress any sanitary surveys to date. It would be useful if the definition could be clarified at the EU level so that a more consistent approach is taken.

3. Problems in applying the requirements of the regulations

Practical experience has shown that there have been problems in applying the elements of regulation quoted above in the Introduction. In particular it may be difficult to obtain information on the following aspects of potential sources of contamination:

- variations in human populations with season
- Variation in waste-water treatment during the year
- variation in animal numbers with season

For some of these, the information may not presently be collected as the environmental regulators do not have any requirement to do so. In other cases, for example, animal numbers at the farm level, the information may be collected by one agency but may not be made available to that doing the sanitary survey due to confidentiality issues.

Another problem relates to the requirement to “determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area”. In some areas, even bathymetric data may not be available and, in many, information on tide and wind-driven currents may not be accessible. The availability of information on tidal currents often depends on the area being of importance to naval or large merchant ships or to it having been the subject of studies for other purposes, e.g. large sewage improvement schemes. In addition, local observation (e.g. at time of shoreline survey) shows that for many areas small-scale variation (wetting/drying areas, counter-currents, turbulence) may significantly modify larger scale trends which are determined by modelling or other assessment techniques.

4. Problems in applying the GPG recommendations

The recommendations in the GPG relating to the acquisition of data are partly based on the requirements of regulations and partly on that deemed necessary to inform the sampling plan. For example, it recommends that detailed information is obtained for sewage discharges, including the flow and microbial content. Acquisition of this data should be the responsibility of the dischargers or environmental regulators. In practice, it is difficult to obtain data on actual flows and the microbial content is only assessed for very specific purposes. In general, estimates of these have to be made on the basis of generic characteristics described in the scientific literature (e.g. Kay, *et al.*, 2008). Although spot measurements and samples may be taken at the time of the shoreline survey, it would take a significant amount of resource to determine loadings for a number of discharges in an area over a range of conditions.

4.1. Randomised versus worst case sampling

For randomised sampling, sample dates and times are determined on a random basis. Ideally they should be identified in advance to exclude any possible bias. In practice, such sampling may be undertaken on a pseudo-random basis, excluding frank bias (Younger, *et al.*, 2003).

Worst-case sampling refers to the timing of sampling with respect to factors known to significantly influence high results. These may include rainfall, season, spring/neap tide, low/high tide, wind direction and speed (Lee & Morgan, 2003; Younger, *et al.*, 2003). The approach was included in the GPG following consideration of the “Adverse Pollution Conditions” approach under the United States National Shellfish Sanitation Program (US FDA 2007). For worst-case sampling, the GPG recommended that sampling dates and times should be identified which were likely to produce the highest levels of contamination. The factors influencing the selection of these would be identified using the outcome of the sanitary survey.

Further experience has led to consideration as to whether such an approach is generally realistic in practice. As identified above, it is likely that several interacting factors will have to coincide to produce the highest results at a particular monitoring point. Taking all of the factors into account may limit the potential dates and times too much for a practical sampling programme, especially when consideration has to be given to aspects of tide, weather and sample transport times. These restrictions are greater for programmes based on shellfish samples than those based on water samples.

It would be simpler if some of these factors could be represented spatially instead of temporally. Figure 3 shows two examples where this may be possible. Figures 3a and 3b show a shellfish bed potentially impacted by sewage outfalls (continuous and intermittent) from two centres of population. Figure 3a shows the winter situation where the populations are approximately equivalent. Figure 3b shows the summer situation in which one town has a large influx of tourists. In the absence of other factors, a sampling point may be located to detect this effect, without having to take the change into account in the sampling programme.

Figures 3c and 3d relate to an actual mussel fishery impacted by a nearby outfall. The mussels were harvested by hand and thus could only be accessed at low tide. The graph of *E. coli* results shows that higher results were obtained at the downstream sampling point than at the upstream one. It is presumed that this was because the downstream point had been sampled shortly after being exposed to contaminated seawater while the upstream point had had relatively clean seawater flowing over it for several hours as the tide ebbed. It is anticipated that higher results would have been obtained at the upstream point if it had been possible to sample there after the tide had been flooding. Again, sampling point location could be used to represent what was essentially a temporal effect. In practice, harvesting was prohibited at this location.

It may be possible to extend these approaches, at least in part, to spring/neap tidal cycle and to rainfall and river flow effects, among others.

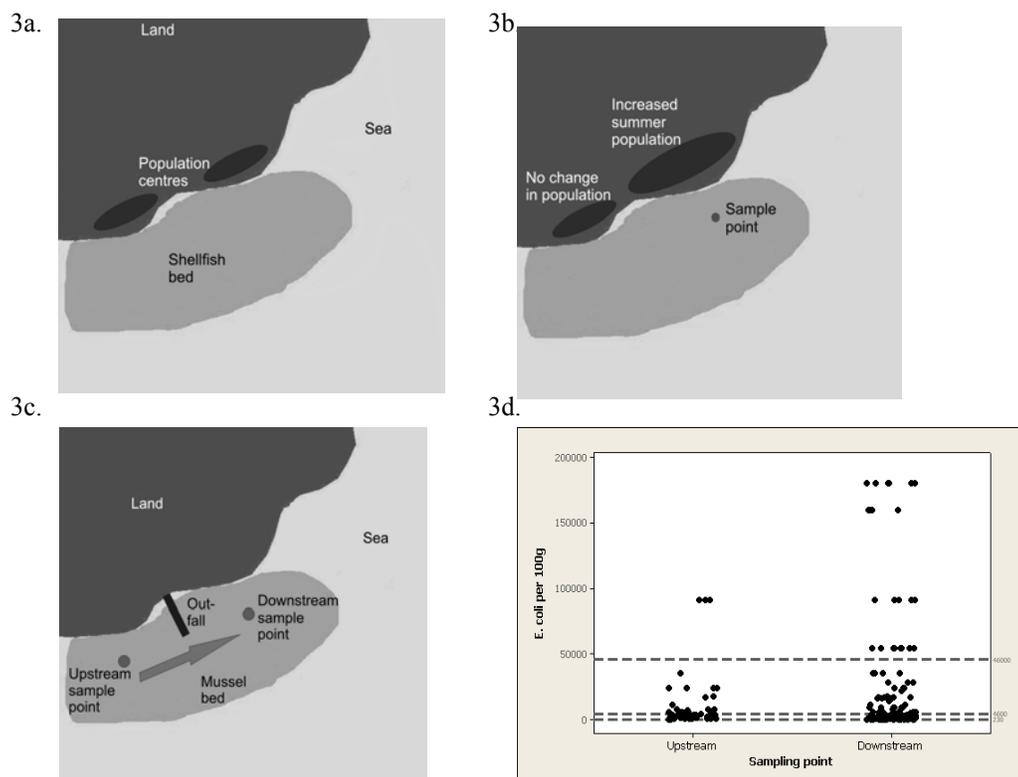


Figure 3. Examples where temporal pollution effects may be represented spatially by sample point location

3a & b – seasonal effects 3c & d – tidal effects

4.2. Existing GPG recommendations on sanitary survey data analysis

The EU Working Group that developed the GPG decided not to recommend specific ways of assessing data, partly because there had been no experience at that time in undertaking sanitary surveys as defined in the EU regulation. The GPG recommends undertaking one of the following:

- Qualitative assessment - for each potential source, an assessment should be made as to whether it will contribute to the microbial load at the bivalve mollusc fisher
- Quantitative assessment - where the contribution from a source cannot be discounted on the basis of a qualitative assessment, but where the significance of the impact is uncertain, a quantitative assessment may be justified

However, experience has shown that sanitary surveys need to consider a wide range of disparate data - sewage discharges, diffuse sources, weather, microbiological data on sea and fresh water, microbiological data on shellfish, and hydrography. These data, some of which are numeric and some of which are descriptive, need to be synthesized into an overall assessment to inform the sampling plan (and other outcomes, such as extent of the classified production area).

Scientists tend to rank numeric data, e.g. historical microbiological results, over other information such as that relating to sources of potential contamination, even though the numeric data may not be directly relevant to the assessment. For example, historical samples for microbiological testing may not have been taken at locations that would detect the impact of the main sources of pollution. It would therefore be beneficial to review and expand the general guidance on data assessment, bearing in mind that each harvesting area has its own unique characteristics and spectrum of available data sets. Any new recommendations would therefore need to comprise an assessment framework and not be prescriptive.

5. International Workshop on Sanitary Surveys

An International Workshop on the Application of Sanitary Surveys was held at Cefas Weymouth in September 2008 and was jointly organised by the CRL and the US Food and Drug Administration. Forty-one participants from ten countries attended the workshop which covered the principles, requirements and practice of EU and US systems. It also included consideration of the approaches taken in Australia, Canada and Korea, where the programmes accommodate one or both of the EU and US systems, but with their own unique elements. The workshop also included field demonstrations of rhodamine dye tracing, fieldwork exercises, and case studies from both the EU and US.

The workshop resulted in a number of recommendations covering the following areas:

- Importance of sanitary surveys in shellfish hygiene programmes
- Understanding Wastewater Treatment Plant effectiveness and impact (including viruses)
- Value of source tracking in supplementing sanitary surveys
- Need for further research to underpin programmes
- Determining equivalency of approaches
- Problem of dual systems
- Assess success using health outcomes
- Need for effective enforcement within shellfish hygiene programmes

The detailed recommendations are available on the CRL website (CRL 2007). There are plans to hold a follow-up workshop in the United States in 2010.

6. Conclusions

Sanitary surveys are internationally acknowledged as a necessary basis for microbiological monitoring and classification of bivalve mollusc harvesting areas. They are now a requirement of the European Food Hygiene Regulations and recommendations on their conduct have been made in the CRL GPG. Progress is being made in Europe with implementation. However, there are problems with applying some of the requirements in both the regulations and the GPG recommendations, primarily due to difficulties in obtaining the appropriate data. In this regard, it would be helpful if the data were collected by the relevant authorities (presumably those responsible for environmental regulation) and made available to those agencies undertaking the sanitary surveys. The GPG recommendations also need to be revisited to take account of practical experience gained in undertaking sanitary surveys within the European Framework.

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